

02-23-05

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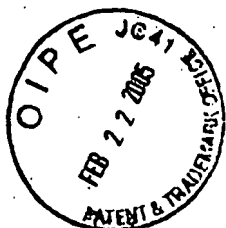
TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/628,792	
	Filing Date	07/28/2003	
	First Named Inventor	Jon A. Wolff	
	Art Unit	1654	
	Examiner Name	J. Ha	
Total Number of Pages in This Submission	>100	Attorney Docket Number	Mirus.040.01

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
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<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	Mark K. Johnson	
Signature		
Date	02/21/2005	

CERTIFICATE OF TRANSMISSION/MAILING		
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Typed or printed name	Kirk Ekena	
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/628,792
Applicants : Jon A. Wolff
Filed : 07/28/2003
Art Unit : 1654
Examiner : J. Ho
Docket No. : Mirus.040.01

For: **Delivery of Molecules and Complexes to Mammalian Cells in Vivo**

Commissioner of Patents
PO Box 1450
Alexandria, VA 2231-1450

INFORMATIONAL STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449.

<u>US patent</u>		
<u>Patent No.</u>	<u>Applicant</u>	<u>Issue date</u>
US-5,521,291	Curiel, David T.	05/28/1996
US-5,580,859	Felgner, Philip L.	12/03/1996
US-5,583,020	Sullivan, Sean	12/10/1996
US-5,598,531	Nabel, Elizabeth	12/16/1997
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US-5,922,687	Mann, Michael J.	07/13/1999
US-6,180,784	Wolff, Jon A. et al.	01/30/2001
US-2003-0143204	Lewis, David et al.	07/03/2003
US-2003-0125281	Lewis, David et al.	07/03/2003

Foreign Patent Publications

<u>Publication No.</u>	<u>Applicant</u>	<u>Publication date</u>
WO 99/31982 Stedman		07/01/1999

REFERENCES CITED

1. Acsadi Get al. "Direct gene transfer and expression into rat heart in vivo" The New Biologist; 1991 Vol. 3 no. 1 pp. 71-81
2. Boulikas, Teni, "Gene Therapy to Human Diseases: Ex Vivo and In Vivo Studies (Review)." International Journal of Oncology; 1996; vol. 9; pp. 1239-1251.
3. Budker V et al. "Naked DNA delivered intraportally expresses efficiently in hepatocytes." Gene Therapy; 1996 Vol. 3 No. 7 pp. 593-598.
4. Budker V et al. "The efficient expression of intravascularly delivered DNA in rat muscle," Gene Therapy; 1998 Vol. 5 no. 2 pp. 272-276
5. Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," Circ. Res; 1992 Vol. 71 pp. 27-33
6. Chowdhury JR et al. "Long-term improvement of hypercholesterolemia after ex vivo gene therapy in LDLR-deficient rabbits," Science; 1991 Vol. 254 pp. 1802-1805
7. Coll JL et al. "In Vivo Delivery to Tumors of DNA Complexed With Linear Polyethylenimine." Human Gene Therapy; 1999 Vol. 10 pp. 1659-1666.
8. Ferry N et al. "Retroviral-mediated gene transfer into hepatocytes in vivo ," Proc Natl Acad Sci USA; 1991 Vol. 88 pp. 8377-8381
9. French, Brent A., Et al., "Cellular and Molecular Cardiology: Percutaneous Transluminal In Vivo Gene Transfer by Recombinant Adenovirus in Normal Porcine Coronary Arteries, Atherosclerotic Arteries, and Two Models of Coronary Restenosis." Circulation; November 1994; vol. 90(5); pp. 2402-2413.
10. Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." Nature; 1999 Vol. 5 no. 4 pp. 439-443
11. Hengge UR et al. "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," Nature Genetics; 1995 Vol. 10 pp. 161-166


12. Hickman MA et al. "Gene expression following direct injection of DNA into liver," Human Gene Therapy; 1994 Vol. 5 pp. 1477-1483
13. Jaffe HA et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," Nat. Genet; 1992 Vol. 1 pp. 372-378
14. Kaleko M et al. "Persistent gene expression after retroviral gene transfer into liver cells in vivo," Hum Gene Ther; 1991 Vol. 2 pp. 27-32
15. Kaneda Y et al. "Increased expression of DNA cointroduced with nuclear protein in adult rat liver," Science; 1989 Vol. 243 pp. 375-378
16. Kaneda Y et al. "Introduction and expression of the human insulin gene in adult rat liver," J Biol Chem; 1989 Vol. 264 pp. 12126-12129
17. Kawabata K et al. "The Fate of Plasmid DNA After Intravenous Injection in Mice: Involvement of Scavenger Receptors in Its Hepatic Uptake." Pharmaceutical Research; 1995 Vol. 12 No. 6 pp. 825-830.
18. Kay MA et al. "Hepatic gene therapy: persistent expression of human alpha 1-antitrypsin in mice after direct gene delivery in vivo," Hum Gene Ther; 1992 Vol. 3 pp. 641-647
19. Ledley FD et al. "Retroviral gene transfer into primary hepatocytes: implications for genetic therapy of liver-specific functions," PNAS; 1987 Vol. 84 pp. 5335-5339
20. Li Q et al. "Assessment of recombinant adenoviral vectors for hepatic gene therapy," Hum. Gene Ther; 1993 Vol. 4 pp. 403-490
21. Liu F et al. "Hydrodynamics-based transfection in animals by systemic administration of plasmid DNA." Gene Therapy; 1999 Vol. 6 pp. 1258-1266.
22. Liu Y et al. "Cationic Liposome-Mediated Intravenous Gene Delivery." J Biol Chem; 1995 Vol. 270 No. 42 pp. 24864-24870.
23. Malone RW et al. "Dexamethasone enhancement of gene expression after direct hepatic DNA injection," J Biol Chem; 1994 Vol. 269 pp. 29903-29907
24. Metrikin DC et al. "Intravitreal drug administration with depot devices." Curr Opin Ophthalmol; 1994 Vol. 5 No. 3 pp. 21-29.
25. Meyer KB et al. "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," Gene Ther; 1995 Vol. 2 pp. 450-460

26. Milas M et al. "Isolated limb perfusion in the sarcoma-bearing rat: a novel preclinical gene delivery system," Clin Cancer Res; 1997 Vol. 3 no. 12 Pt. 1, pp. 2197-203
27. Rekhter, Mark D. MD, PhD, Et al., "Graft Permeabilization Facilitates Gene Therapy of Transplant Arteriosclerosis in a Rabbit Model." Circulation; September 29, 1998; vol. 98(13); pp. 1335-1341.
28. Rekhter, Mark D., Et al., "Gene Transfer Into Normal and Atherosclerotic Human Blood Vessels." Circ. Res.; 1998; vol. 82; pp. 1243-1252.
29. Riessen et al. "Arterial gene transfer using pure DNA applied directly to a hydrogel-coated angioplasty balloon," Human Gene Ther; 1993 Vol. 4 pp. 749-758
30. Ross, Gail, Et al., "Gene Therapy in the United States: A Five-Year Status Report." Human Gene Therapy; September 10, 1996; vol. 7; pp. 1781-1790.
31. Sikes M et al. "In vivo gene transfer into rabbit thyroid follicular cells by direct DNA injection," Hum. Gene Ther; 1994 Vol. 5 p. 837-844
32. Simari, Robert D., Et al., "Regulation of Cellular Proliferation and Intimal Formation Following Balloon Injury in Atherosclerotic Rabbit Arteries." Gene Therapy for Atherosclerotic Arteries; J. Clin. Invest.; July 1996; vol. 98, no. 1; pp. 225-235.
33. Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," PNAS; 1983 Vol. 80 pp. 7128-7131
34. Stratford-Perricaudet LD et al. "Evaluation of the transfer and expression in mice of an enzyme-encoding gene using a human adenovirus vector," Hum. Gene Ther; 1990 Vol. 1 pp. 241-256
35. Vile RG et al. "In vitro and in vivo targeting of gene expression to melanoma cells," Cancer Res; 1993 Vol. 53 pp. 962-967
36. Von Der Leyen, Heiko, E., Et al., "A Pressure-Mediated Nonviral Method For Efficient Arterial Gene and Oligonucleotide Transfer." Human Gene Therapy 1999 Vol. 10 pp. 2355-2364.
37. Wolff JA et al. "Direct gene transfer into mouse muscle in vivo," Science; 1990 Vol. 247 pp. 1465-1468
38. Wolff JA et al. "Expression of retrovirally transduced genes in primary cultures of adult rat hepatocytes," Proc Natl Acad Sci USA; 1987 Vol. 84 pp. 3344-3348

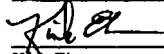
39. Zhang G et al. "Efficient Expression of Naked DNA Delivered Intraarterially to Limb Muscles of Nonhuman Primates." Hum Gene Ther; 2001 Vol. 12 pp. 427-438.
40. Zhang G et al. "Expression of Naked Plasmid DNA Injected into the Afferent and Efferent Vessels of Rodent and Dog Livers." Human Gene Therapy; 1997 Vol. 8 pp. 1763-1772.
41. Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA." Hum Gene Ther; 1999 Vol. 10 pp. 1735-1737.
42. Zhu N et al. "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science; 1993 Vol. 261 pp. 209-211.

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

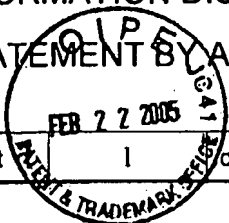
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Kirk Ekena

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/628,792
		Filing Date	07/28/2003
		First Named Inventor	Jon A. Wolff
		Art Unit	1654
		Examiner Name	J. Ho
Sheet 1 of 3	Attorney Docket Number	Mirus.040.01	



U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/J.H./		US-5,521,291	05/28/1996	Curiel, David T.	
		US-5,580,859	12/03/1996	Felgner, Philip L.	
		US-5,583,020	12/10/1996	Sullivan, Sean	
		US-5,598,531	12/16/1997	Nabel, Elizabeth	
		US-5,744,335	04/28/1998	Wolff, Jon A. et al.	
		US-5,922,687	07/13/1999	Mann, Michael J.	
		US-6,180,784	01/30/2001	Wolff, Jon A. et al.	
		US-2003-0143204	07/03/2003	Lewis, David et al.	
		US-2003-0125281	07/03/2003	Lewis, David et al.	

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner Initials	Document Number	Publication Date	Country or Patent Office	Class	Sub Class	Transl. yes no
/J.H./	WO 99/31982	07/01/99	US			

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.		T
/J.H./		Acsadi Get al. "Direct gene transfer and expression into rat heart in vivo" The New Biologist; 1991 Vol. 3 no. 1 pp. 71-81	
		Boulikas, Teni, "Gene Therapy to Human Diseases: Ex Vivo and In Vivo Studies (Review)." International Journal of Oncology; 1996; vol. 9; pp. 1239-1251.	
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		Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." <i>Nature</i> ; 1999 Vol. 5 no. 4 pp. 439-443	
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		Jaffe HA et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," <i>Nat. Genet</i> ; 1992 Vol. 1 pp. 372-378	
		Kaleko M et al. "Persistent gene expression after retroviral gene transfer into liver cells in vivo," <i>Hum Gene Ther</i> ; 1991 Vol. 2 pp. 27-32	
		Kaneda Y et al. "Increased expression of DNA cointroduced with nuclear protein in adult rat liver," <i>Science</i> ; 1989 Vol. 243 pp. 375-378	
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✓		Zhu N et al. "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science; 1993 Vol. 261 pp. 209-211.	

Examiner Signature	/Julie Ha/	Date Considered	Feb. 22, 2005
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12 29 05

JFW

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	TRANSMITTAL FORM	
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	First Named Inventor	Jon A. Wolff
	Art Unit	1654
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Total Number of Pages in This Submission		10
Attorney Docket Number		Mirus.040.01

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Mirus Bio Corporation		
Signature			
Printed name	Kirk Ekena		
Date	12/28/2005	Reg. No.	56,672

CERTIFICATE OF TRANSMISSION/MAILING

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Typed or printed name	Kirk Ekena	Date	12/28/2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/628,792
Applicants : Jon A. Wolff
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Art Unit : 1654
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For: **Delivery of Molecules and Complexes to Mammalian Cells in Vivo**

Commissioner of Patents
PO Box 1450
Alexandria, VA 2231-1450

INFORMATIONAL STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449.

No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

US patent publication

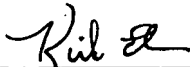
<u>Patent No.</u>	<u>Applicant</u>	<u>date</u>
US 2001/0009904	Wolff et al	July 26, 2001

REFERENCES CITED

Song J et al. "Influence of Injection Site, Microvascular Pressure and Ultrasound Variables on Microbubble-mediated Delivery of Microspheres to Muscle." J. Am. Coll. Cardiol. 2002 Vol. 39 No. 4, p. 726-731.

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

Respectfully submitted,



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United States Postal Service mail to: Commissioner for
Patents, PO Box 1450, Alexandria, VA 22313-1450 on:

12/28/2005



Kirk Ekena

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Sheet	1	of	1	Attorney Docket Number	Mirus.040.01

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number – Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/J.H./		US-2001-0009904	07/26/2001	Wolff J. et al.	

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

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/J.H./		Song J et al. "Influence of Injection Site, Microvascular Pressure and Ultrasound Variables on Microbubble-mediated Delivery of Microspheres to Muscle." J. Am. Coll. Cardiol. 2002 Vol. 39 No. 4, p. 726-731.	

Examiner Signature	/Julie Ha/	Date Considered	Dec. 28, 2005
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